

NATIONAL SURVEY OF HOSPITAL COAGULATION LABORATORIES



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
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CDC
CENTERS FOR DISEASE CONTROL
AND PREVENTION

National Survey of Hospital Coagulation Laboratories

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This survey is being conducted by Analytical Sciences, Inc. (ASI) for Centers for Disease Control and Prevention (CDC). All information will be treated in a confidential manner. No identifying information about you will be given to CDC or any other party. The number on the questionnaire is for tracking purposes only and will be kept separate from your responses by a secured delinking process. *Please do not put your name on this questionnaire.*

Please check the box at the end of the survey questionnaire if you would like a report of the survey findings.

If you have any questions or comments about this survey, please contact Dr. Jack Leiss at ASI at 800-451-3930 or by email at jleiss@asciences.com.

It takes about 30 minutes to complete the questionnaire. Please mark either a check or X in the indicated response boxes, i.e. [✓] or [X]. Your participation is greatly appreciated.

A note to respondents concerning confidentiality:

This survey is being conducted under the authority of Section 301 of the Public Health Service Act. The purpose of this survey is to provide CDC with information it needs to assess the state of coagulation testing in US hospital laboratories. Advanced measures are in place to protect your privacy. Questionnaires will be numbered, and the files linking these numbers to your responses will be available only to authorized ASI personnel directly involved with the survey. Individually identified data will not be sent to CDC; the data files sent to CDC will have a record number that is different from the questionnaire number, and the file linking the record number to the questionnaire number will be available only to authorized ASI personnel. If you have any questions about the confidentiality of your responses, please call Dr. Jack Leiss at ASI at 800-451-3930.

A note to respondents concerning respondent burden:

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, NE, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0505).

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1. Does your laboratory perform any coagulation testing?

1 Yes

2 No → *The rest of the questionnaire is not applicable to your laboratory, and you have completed the survey. Please return the questionnaire in the enclosed envelope. Your participation is greatly appreciated.*

This first set of questions relates to the collection of coagulation specimens.

2. Does your laboratory use coagulation test requisition forms?

1 No → *Go to Question 3.*

2 Yes → Please indicate what diagnostic and/or medication information is requested on the requisition form for a coagulation test in your laboratory.

Information	Requested	Not Requested
Diagnosis	1 <input type="checkbox"/>	2 <input type="checkbox"/>
ICD-9 Code	1 <input type="checkbox"/>	2 <input type="checkbox"/>
CPT Code	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Oral Contraceptive use	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Aspirin use	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Coumadin use	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Heparinoid use	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Heparin (unfractionated) use	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Low Molecular Weight Heparin (LMWH) use	1 <input type="checkbox"/>	2 <input type="checkbox"/>

3. Which of the following are included in your policies and procedures as reasons for rejecting coagulation specimens in your laboratory?

- Insufficiently labeled specimen containers 1 Yes 2 No
- Improperly anti-coagulated specimen 1 Yes 2 No
- Requisition and specimen have conflicting patient information..... 1 Yes 2 No
- Label does not have hospital Medical Record Number (ID number) 1 Yes 2 No
- Specimen collected via indwelling catheter 1 Yes 2 No
- Specimen stored at an inappropriate temperature 1 Yes 2 No
- Specimen transport time exceeds recommended time frame 1 Yes 2 No
- Specimen is clotted 1 Yes 2 No
- Specimen is hemolyzed..... 1 Yes 2 No

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The following questions ask about the Prothrombin Time (PT) assay.

4. Does your coagulation laboratory perform the PT assay?

- 1 No → *Go to Question 13.*
- 2 Yes → *Please answer Questions 5 - 12.*

5. What is the concentration of sodium citrate that is used in your laboratory for samples tested for the PT assay? (*Check all that apply.*)

- 1 3.2%
- 2 3.8%

6. How does your coagulation laboratory report the PT results? (*Check all that apply.*)

- | | | |
|---------------------------|--------------------------------|-------------------------------|
| Seconds..... | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| INR..... | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| Therapeutic PT Ratio..... | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |

7. Does your laboratory conduct in-house evaluations to establish reference ranges for the PT assay?

1 No → How does your laboratory establish the PT reference range?

- 1 Using published values
- 2 Using manufacturer's insert
- 3 Other (*Please specify.*) _____

2 Yes → Please indicate the minimum number of participants used in the in-house evaluation for the establishment of the PT assay reference range in your laboratory. (*Check only one.*)

- 1 20 or fewer
- 2 21 - 39
- 3 40 - 59
- 4 60 - 119
- 5 120 - 199
- 6 200 or more

8. Does your laboratory determine sensitivity of the PT assay to heparin?

- 1 Yes
- 2 No

9. What is the primary PT method used in your coagulation laboratory? (*Choose only one.*)

- 1 Manual
- 2 Mechanical
- 3 Optical
- 4 None of the above

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10. Please indicate which reagent(s) is/are used for the PT assay in your coagulation laboratory.
(Check all that apply.)

- 1 Hemoliance Brain Thromboplastin
- 2 Dade Behring Thromboplastin C Plus
- 3 Innovin
- 4 Pacific Hemostasis D
- 5 OTC Simplastin L
- 6 Other

The use of trade names is for identification purposes only and does not constitute endorsement by CDC or HHS.

11. Does your laboratory select a PT-thromboplastin reagent that is insensitive to heparin in the heparin therapeutic range? 1 Yes 2 No

12. What is the international sensitivity index (ISI) value for the thromboplastin lot currently being used for PT testing?
(Please fill in the blank.) _____

The following questions ask about the Activated Partial Thromboplastin Time (aPTT) assay.

13. Does your coagulation laboratory perform the aPTT assay?

- 1 No → Go to Question 16.
- 2 Yes → Please answer Questions 14 and 15.

14. Does your coagulation laboratory have an aPTT therapeutic range for heparin?

- 1 No → Go to Question 15.
- 2 Yes → Please answer Questions A - D.

A. Does your laboratory report the aPTT therapeutic range for heparin when the assay is used to monitor heparin therapy?..... 1 Yes 2 No

B. Does your laboratory indicate the corresponding heparin concentration with the aPTT results? 1 Yes 2 No

C. Please indicate which of the following practices your laboratory performs to determine the aPTT therapeutic range for heparin.

- Uses samples from patients on heparin therapy to compare a new **heparin lot** to an old **heparin lot** 1 Yes 2 No
- Uses samples from patients on heparin therapy to compare a new **reagent lot** to an old **reagent lot** 1 Yes 2 No
- Uses heparin “spiked” samples to compare a new **heparin lot** to an old **heparin lot** 1 Yes 2 No
- Uses heparin “spiked” samples to compare a new **reagent lot** to an old **reagent lot** 1 Yes 2 No
- Protamine sulfate titration 1 Yes 2 No
- Anti-Xa Assay 1 Yes 2 No
- Other (*Please specify.*) _____

D. Please indicate when your laboratory would reconfirm the aPTT therapeutic range for heparin. (*Check all that apply.*)

- 1 When new **reagents** are implemented
- 2 When new **reagent lots** are implemented
- 3 When new **instrumentation** is implemented
- 4 After a specified time period (e.g., yearly)
- 5 None of the above

15. What practices does your laboratory adhere to in relation to the duration of time between specimen collection and performance of aPTT for patients treated with unfractionated heparin?

- Specimens are kept at room temperature prior to testing..... 1 Yes 2 No
- Specimens are kept at 4°C prior to testing 1 Yes 2 No
- Specimens are assayed within 4 hours after phlebotomy 1 Yes 2 No
- Specimens are centrifuged within 1 hour of collection..... 1 Yes 2 No

The following questions ask about assays for von Willebrand's disease.

16. Does your coagulation laboratory perform von Willebrand Factor Antigen (vWF Ag)?

- 1 No → *Go to Question 19.*
- 2 Yes → *Please answer Questions 17 and 18.*

17. Does your laboratory report an ABO specific reference range for the vWF Ag assay?

- 1 Yes 2 No

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18. Which methodology for vWF Ag is used in your coagulation laboratory? (*Check all that apply.*)

- 1 ELISA
- 2 Electrophoresis
- 3 LIA (Latex Immunoassay)
- 4 Other (*Please specify.*) _____

19. Does your laboratory perform von Willebrand Factor Activity (Ristocetin CoFactor Activity)?

- 1 No → *Go to Question 20.*
- 2 Yes → Which methodology for Ristocetin CoFactor Activity is used in your coagulation laboratory? (*Check all that apply.*)
 - 1 Platelet Aggregometry
 - 2 ELISA
 - 3 Collagen Binding Assays
 - 4 Other (*Please specify.*) _____

20. Does your laboratory provide results for von Willebrand Factor Multimers?

- 1 No → *Go to Question 21.*
- 2 Yes → Under what circumstances does your laboratory perform vWF Multimers?
 - When the Ristocetin CoFactor is decreased..... 1 Yes 2 No
 - When the Ristocetin CoFactor is disproportionately decreased relative to the vWF Ag..... 1 Yes 2 No
 - When the Antigen and Activity are both low 1 Yes 2 No
 - Only if the Ristocetin Induced Platelet Aggregation indicates a Type II B von Willebrand's disease 1 Yes 2 No
 - Only when ordered by a clinician 1 Yes 2 No

The following questions concern practices and/or test menu selections for a Thrombosis or Hypercoagulability Workup.

21. Does your laboratory usually perform the functional test (activity) for Protein S before the antigenic assay?

- 1 No → *Go to Question 22.*
- 2 Yes → If the results of the functional test (activity) for Protein S are decreased, does your laboratory routinely perform:
 - The antigenic assay to differentiate Type I deficiency from Type II? 1 Yes 2 No
 - The Protein S Antigen, Free and Total? 1 Yes 2 No

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22. Does your laboratory perform the Activated Protein C (APC) Resistance assay?

- 1 No → Go to Question 23.
- 2 Yes → If the results of the APC indicate resistance to APC, do you obtain results for the Factor V Leiden Mutation? 1 Yes 2 No

The following questions concern an algorithm for diagnosing a Lupus Anticoagulant.

23. Does your laboratory offer a Lupus Anticoagulant Profile (LAC Profile)? 1 Yes 2 No

24. If a PT result is prolonged, when would your laboratory routinely perform a mixing study on the specimen? (Check only one.)

- 1 Our laboratory does not offer mixing studies for PT
- 2 Only if there is an additional order for the mixing study
- 3 Always when PT is prolonged
- 4 Only if PT was ordered as part of the LAC Profile
- 5 Other

25. If an aPTT result is prolonged, when would your laboratory routinely perform a mixing study on the specimen? (Check only one.)

- 1 Our laboratory does not offer mixing studies for aPTT → Go to Question 27.
- 2 Only if there is an additional order for the mixing study
- 3 Always when aPTT is prolonged
- 4 Only if aPTT was ordered as part of the LAC Profile
- 5 Other

26. If the results of the mixing study for aPTT do not correct to normal, would your laboratory routinely initiate a workup to diagnose a Lupus Anticoagulant?

- 1 No → Go to Question 27.
- 2 Yes → Please indicate which of the following are routinely performed for diagnosing a Lupus Anticoagulant.

- Dilute Russell Viper Venom Time (DRVVT)..... 1 Yes 2 No
- Lupus Sensitive aPTT 1 Yes 2 No
- Kaolin Clotting Time (KCT) 1 Yes 2 No
- Hexagonal (II) Phase Phospholipid Assay (Staclot LA)..... 1 Yes 2 No
- Platelet Neutralization Procedure (PNP)..... 1 Yes 2 No
- Tissue Thromboplastin Inhibition Test (TTIT) 1 Yes 2 No

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The next questions relate to the monitoring of Low Molecular Weight Heparin (LMWH) therapy.

27. Does your laboratory monitor LMWH therapy?

- 1 No → Go to Question 29.
- 2 Yes → Please answer Question 28.

28. Please indicate which of the following assays your coagulation laboratory uses to monitor LMWH.

- aPTT 1 Yes 2 No
 - Factor Xa (Inhibitor Assay) 1 Yes 2 No
 - Thrombin Inhibitor Assay (HEP Test) 1 Yes 2 No
 - Anti-Xa 1 Yes 2 No → If "No", Go to Question 29.
- ↳ If "Yes" for Anti-Xa, please answer Questions A – D.

A. What calibrator is used for the Anti-Xa assay in your coagulation laboratory?
(Check all that apply.)

- 1 LMWH supplied by pharmacy
- 2 Internal Standard LMWH
- 3 Internal Standard Unfractionated Heparin
- 4 Unfractionated Heparin
- 5 Heparinoid
- 6 Other

B. Does your laboratory use different calibration curves
for **LMWH and unfractionated heparin**? 1 Yes 2 No

C. Does your laboratory use different calibration curves
for **each type of LMWH**? 1 Yes 2 No

D. How long after subcutaneous administration of LMWH does your laboratory recommend
that the specimen be collected for optimal testing of Anti-Xa? (Check only one.)

- 1 Our coagulation laboratory does not recommend a time for testing
- 2 Immediately after injection
- 3 2 hours after injection
- 4 Between 2 and 4 hours after injection
- 5 4 hours after injection
- 6 5 hours or more after injection
- 7 Before the next dose is administered
- 8 Do not know
- 9 None of the above

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The following question asks about the availability of specific coagulation tests in your laboratory.

29. Please indicate which of the following coagulation tests are performed **in-house** for clinical purposes (e.g., diagnosis, monitoring, screening, or treatment). Exclude assays performed for research purposes only.

- Bleeding Time 1 Yes 2 No
- Activated Clotting Time..... 1 Yes 2 No
- Thrombin Time 1 Yes 2 No
- Fibrinogen..... 1 Yes 2 No
- Fibrin(ogen) Degradation Products 1 Yes 2 No
- D-Dimer 1 Yes 2 No
- Euglobulin Clot Lysis Time 1 Yes 2 No
- Factor II Activity 1 Yes 2 No
- Factor V Activity..... 1 Yes 2 No
- Factor V Leiden 1 Yes 2 No
- Factor VII Activity..... 1 Yes 2 No
- Factor VIII Activity..... 1 Yes 2 No
- Factor VIII Antigen..... 1 Yes 2 No
- Bethesda Assay-Inhibitor Titer 1 Yes 2 No
- Factor IX Activity..... 1 Yes 2 No
- Factor X Activity..... 1 Yes 2 No
- Factor X Antigen..... 1 Yes 2 No
- Plasminogen (functional) Assay 1 Yes 2 No
- Plasminogen Antigen..... 1 Yes 2 No
- Heparin Assay (Anti-Xa) 1 Yes 2 No
- Platelet Aggregation Study 1 Yes 2 No
- Platelet Antibody..... 1 Yes 2 No
- Ristocetin Titration of Platelet Aggregation 1 Yes 2 No
- von Willebrand Factor Multimers 1 Yes 2 No

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The following questions refer to certain aspects of reporting coagulation test results.

30. Using a check mark, please indicate what test result information, interpretations, and recommendations are provided on your coagulation test report for PT, aPTT, vWF Antigen, and Protein C assays. (Check all that apply.)

	PT	aPTT	vWF Antigen	Protein C
Test Not Performed	1	1	1	1
Measurement Units (e.g., seconds, %)	2	2	2	2
Specimen comments (if needed)	3	3	3	3
Reference ("Normal") ranges	4	4	4	4
Therapeutic ranges	5	5	5	5
Testing methodology/reagent	6	6	6	6
Possible drug interactions	7	7	7	7
Suggested diagnoses	8	8	8	8
Written interpretation	9	9	9	9
No test result interpretation	10	10	10	10
Recommendations for further testing	11	11	11	11
Recommendations for treatment	12	12	12	12
Recommendations to test family members	13	13	13	13
No recommendation	14	14	14	14

31. Does your laboratory offer consultation services for coagulation testing?

- 1 No → Go to Question 32.
 2 Yes → Please answer Questions A - C.

A. Please indicate when coagulation test reports are reviewed. (Check all that apply.)

- 1 This service is not offered
 2 Upon request by clinician
 3 Upon request by testing personnel
 4 For all specialized tests
 5 None of the above

B. Please indicate who reviews coagulation test reports.
(Check all that apply.)

- 1 This service is not offered
- 2 Laboratory Director
- 3 Pathologist (excluding residents)
- 4 Laboratory Supervisor
- 5 Physicians in training (residents, interns, medical students)
- 6 None of the above

C. Please indicate who provides comments on the coagulation test reports.
(Check all that apply.)

- 1 This service is not offered
- 2 Laboratory Director
- 3 Pathologist (excluding residents)
- 4 Laboratory Supervisor
- 5 Physicians in training (residents, interns, medical students)
- 6 None of the above

The next section relates to the process of reporting results.

32. Does your laboratory report critical values (panic values) for coagulation tests?

- 1 No → Go to Question 33.
- 2 Yes → Please respond to the following:

- Critical values are repeated and documented as "confirmed" 1 Yes 2 No
- Critical values are indicated on the report and no further action is taken..... 1 Yes 2 No
- Critical values are telephoned to the clinician and the call is not always documented..... 1 Yes 2 No
- Critical values are telephoned to the clinician and the call is documented 1 Yes 2 No

33. Under what circumstances would a coagulation test usually be repeated in your laboratory?

- Control(s) is/are out of range 1 Yes 2 No
- Results are outside instrument technical ranges..... 1 Yes 2 No
- Results are outside of the reference ("normal") range 1 Yes 2 No
- Results are critical values (panic values) 1 Yes 2 No
- Results do not agree with previous results (using a predetermined Delta Check range) 1 Yes 2 No

The next question asks about Quality Assurance (QA) procedures.

34. Please indicate if any of the following QA steps are usually taken in your laboratory.

- Specimen label and requisition form are matched 1 Yes 2 No
- Patient information on specimen tube and laboratory
generated labels are matched 1 Yes 2 No
- Instrument printout is compared to reported value 1 Yes 2 No
- Patient's previous results are checked (Delta Check) 1 Yes 2 No
- Critical (Panic) values are reviewed 1 Yes 2 No
- Critical (Panic) values are brought to the immediate
attention of the clinician 1 Yes 2 No
- New analytical methods are validated 1 Yes 2 No
- Calibration of all instruments (analyzers, centrifuges,
refrigerators, etc.) is periodically verified 1 Yes 2 No
- Plasma is checked for a platelet count after centrifugation 1 Yes 2 No
- Specimens are run in duplicate 1 Yes 2 No
- Controls are run in duplicate 1 Yes 2 No

The next section asks about your coagulation laboratory's personnel and resources.

35. Where in your facility is coagulation testing performed? *(Check all that apply.)*

- 1 Core Laboratory
- 2 Coagulation Laboratory
- 3 Hematology Laboratory
- 4 Point-of-Care Testing
- 5 Rapid response (Stat) Laboratory
- 6 None of the above

36. How many FTEs (Full Time Equivalents) does your laboratory have for performing coagulation testing? *(Check only one.)*

- 1 Less than 4
- 2 4 - 9
- 3 10 or more

37. Please indicate which of the following components are included in your competency assessment program for coagulation testing personnel. *(Check all that apply.)*

- 1 Periodic written exam
- 2 Analysis of unknown samples
- 3 Review of procedure manuals
- 4 Direct observation of a task
- 5 Participation in Continuing Education (CE)
- 6 Successful performance of quality control (QC) with documentation of remedial actions
- 7 None of the above

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38. Please indicate the educational degree of the laboratory director who is responsible for coagulation testing.
(Check all that apply.)

- 1 M.D.
- 2 Ph.D.
- 3 Other (Please specify.) _____

39. Please indicate the certifications of the laboratory director who is responsible for coagulation testing.
(Check all that apply.)

- 1 Board Certified in Clinical Pathology (CP)
- 2 Board Certified in Anatomical Pathology (AP)
- 3 Board Certified in Medicine
- 4 Board Certified in Subspecialty of Hematology
- 5 Board Certified in Hematopathology
- 6 Certified by American Association of Bioanalysts (AAB)
- 7 Certified by American Board of Clinical Chemistry (ABCC)
- 8 Certified by National Registry of Clinical Chemistry (NRCC)
- 9 Certified by National Certifying Agency (for Clinical Laboratory Sciences) (NCA)
- 10 Certified by American Society of Clinical Pathologists (ASCP)
- 11 None of the above

40. In your hospital, is there a clinician available for consultation who has expertise in coagulation disorders? 1 Yes 2 No

41. Does your hospital have an anticoagulation outpatient clinic that specializes in the adjustment of oral anticoagulants? 1 Yes 2 No

42. Does your hospital have an outpatient clinic that specializes in the diagnosis and treatment of coagulation disorders? 1 Yes 2 No

The next section addresses Point-of-Care Testing (POCT) for the PT assay.

43. Is POCT currently available for the Prothrombin Time (PT) assay within your hospital?

- 1 No → Go to Page 15.
- 2 Yes → Please answer Questions A - F.

A. Does the laboratory have oversight of coagulation POCT including certification and regulatory compliance? 1 Yes 2 No

B. Where is coagulation POCT performed in your hospital? (Check all that apply.)

- 1 At the bedside
- 2 At a coagulation clinic
- 3 In a satellite laboratory
- 4 In a cardiac catheterization laboratory
- 5 In a dialysis clinic
- 6 In operating rooms
- 7 None of the above

C. Are coagulation POCT results integrated into the laboratory's results reporting system?

- 1 No → Go to Question D.
- 2 Yes → Are coagulation POCT results integrated into the laboratory's reporting system in the order of collection times? 1 Yes 2 No

D. Is the reference range for the POCT PT assay the same as the PT assay reference ("normal") range used by your coagulation laboratory?

- 1 Yes → Go to Question E.
- 2 No → Was the POCT reference ("normal") range established by the same method used to establish the Prothrombin Time reference range for your laboratory?
 - 1 Yes → Go to Question E.
 - 2 No → How was the POCT reference ("normal") range established? (Check all that apply.)
 - 1 In-house testing
 - 2 Manufacturer's insert
 - 3 Published values
 - 4 Other (Please specify.)

E. Which type of QC material is used on the POCT coagulation instrument?
(Check all that apply.)

- 1 Liquid
- 2 Lyophilized
- 3 Electronic
- 4 None of the above

F. How often is QC performed on each coagulation POCT instrument?
(Check all that apply.)

- 1 Once per shift
- 2 Once per day
- 3 Other (Please specify.) _____

